

REMARKS

The Office Action mailed January 14, 2004, has been received and its contents carefully noted. Original claims 1-11 and new claims 14-23 are pending in the application. New claims 12-13 are allowed. New claims 14-16 are dependent claims derived from the ranges set forth in original claim 2. New claims 17-18 are dependent claims derived from the ranges set forth in original claim 3. New claim 19 is a dependent claim derived from the ranges set forth in original claim 4. New claims 20-21 are dependent claims derived from the ranges set forth in original claim 10. New claims 22-23 are dependent claims derived from the ranges set forth in original claim 11. No new matter has been added with this amendment.

The Examiner rejected claims 2-5, 10 and 11 under 35 U.S.C. § 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically with regard to claims 2-4, 10 and 11, the Examiner rejected the recitation of multiple ranges of elements in a single claim. Applicant has amended claims 2-4, 10 and 11 to remove the multiple ranges and added new dependent claims as set forth at the beginning of the Remarks.

In addition, with regard to claims 5, 6, 9, 10 and 11, Applicant has amended these claims to depend from claim 12 which recites the method of preparation of the fibers of the present invention. Applicant submits that the amendments to claims 2-5, 10 and 11 render the rejection under 35 U.S.C. § 112, second paragraph as moot and respectfully requests withdrawal of the rejection.

The Examiner has rejected claims 1, 4, 6 and 8-11 under 35 U.S.C. § 102(b) as being anticipated by WO 98/46818 ("Court"). The Examiner contends that the fibers described in Court are chitosan fibers having the same properties as claimed in claims 1, 4, 6 and 8-11 of the present application. Applicant respectfully traverses this rejection.

Claims 4-6, and 8-11 were amended to depend from the method of claim 12 and, therefore, Applicant submits that the rejection of these claims is rendered moot.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Court fails to teach each and every element of the claimed invention. More specifically claim 1, as amended, claims chitosan that is (1) "capable of absorbing liquid to form a swollen, coherent gel", and (2) "in the form of fibers having an absorption higher than about 20 g/g". The specification of the present invention describes the chitosan fibers as being capable of absorbing liquid by swelling and turning into a cohesive gel. The present invention provides a cohesive gel that allows the wound dressing to be removed in one piece after it has absorbed the maximal amount of liquid (page 3, lines 16-19). The terms "water swelling", and "water gelling but substantially water-insoluble" mean that when the fibers are in contact with aqueous liquid, they will swell by forming a gel. The fiber structure is still detectable and the fibers will turn from non-transparent to transparent. The fibers are sufficiently water-insoluble and coherent so that it is possible to remove them from a wound in one piece (page 5, lines 4-10).

Court does not disclose chitosan fibers having the above characteristics. While the specification of Court states that the claimed fibers should have absorbency of at least 15 g/g, there is no discussion of the coherence of the fibers. The Court reference contains no disclosure of any measurement of the fiber coherence or any data which describes chitosan fibers having any of the characteristics of Applicant's invention.

In addition, Applicant submits that Court is not enabling for a wound dressing as claimed for Applicant's invention, and as such cannot be an anticipating reference under 35 U.S.C. § 102 (b). "A reference itself must have an enabling disclosure to be used as a proper reference. Section 102 (b) of 35 U.S.C. and its predecessor statutes have been interpreted as requiring the description of the invention in a publication to be sufficient to put the public in possession of the

invention.” Ex Parte Gould, 231 USPQ 943 (BPAI 1986). The specification of Court only details production of a wound dressing using alginates and substituted carboxymethyl cellulose. Indeed, the application discloses and claims a wound dressing comprised of previously published alginate and cellulose fibers woven with textile fibers. In contrast, the word “chitosan” appears only once in the entire specification as part of a list of possible fibers to be combined with the textile fibers. “The mere naming of a compound in a reference, without more, cannot constitute description of the compound...” In re Wiggins, James and Gittos, 488 F.2d 538, 179 USPQ 421 (CCPA 1973). Applicant respectfully submits that claims 1, 4, 6 and 8-11 are not anticipated by Court for the reasons stated above and as such request withdrawal of the rejection.

The Examiner has rejected claims 1, 2, and 4-7 under 35 U.S.C. § 103 (a) as being unpatentable over U.S. Patent No. 5,599,916 (“Dutkiewicz et al.”). The Examiner contends that Dutkiewicz discloses absorbent chitosan fibers capable of swelling and gelling and it would have been obvious for one of skill in the art to use the fibers of Dutkiewicz in the wound care device of Applicant’s invention. Applicant respectfully traverses this rejection.

Claims 4-6 were amended to depend from the method of claim 12 and therefore the Applicant submits that rejection of these claims is rendered moot.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. Moreover, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

The burden is on the examiner to establish a *prima facie* case of obviousness of the claimed subject matter over prior art references. In re Deuel, 51 F.3d 1552, 1557, 34 USPQ2d 1210, 1214 (Fed. Cir. 1995). Only after that burden is met must the applicant come forward with

arguments or evidence in rebuttal. Id. To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The Applicant suggests that the Examiner has failed to establish a *prima facie* case of obviousness because Dutkiewicz does not teach each and every element of the claimed invention.

The Applicant respectfully submits that Dutkiewicz does not teach or disclose production of chitosan fibers. Nowhere in the specification is there any description of the preparation of chitosan fibers of any kind. The only instance where the word “fiber” is found in the entire patent, is in column 14, lines 15-16, which states:

"The form of the recovered chitosan salt desired will depend to a large extent on the use for which it is intended. When the chitosan salt is intended for use in absorbent personal care products, it is generally desired that the chitosan salt be in the form of a discrete particle, fiber of flake." (emphasis added)

This statement is obviously a description of the prior art. The Dutkiewicz patent only discloses the preparation of a modified powdered chitosan salt. The salt is prepared by treatment with acid in a solution, and then the dissolved chitosan salt is dried by heat. The resulting salt is then ground and sifted into a powder. This procedure cannot be used to create fibers as they will be dissolved. Furthermore, the resulting composition in the Dutkiewicz patent does not show any cohesiveness and will thus be unsuitable for use in wound dressings. Example 12 and Figure 1 in the instant application shows the difference between treating chitosan powder and the chitosan fibers of the present invention. As one can see from the drawing figure, the powdered chitosan (the wooden stick on the left) does not form a cohesive sheet suitable for use as a wound dressing. Since the Dutkiewicz patent does not teach or suggest all of the elements of claims 1, 2 and 7 of the present invention, it cannot render the claims obvious. Applicant respectfully requests withdrawal of this rejection.

The Examiner rejected claims 3 and 7 under 35 U.S.C. § 103 (a) as unpatentable over Court. The Examiner contends that the choice of ranges for the proportion of length to width for fibers in claim 3 is an obvious design choice. Further, the Examiner states that the choice of designs for the wound dressing in claim 7 was also an obvious design choice. The Applicant respectfully traverses this rejection.

As the Applicant has stated above, to establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). First, Applicant has shown previously that Court does not disclose chitosan fibers having the claimed characteristics. While the specification of Court states that the claimed fibers should have absorbency of at least 15 g/g, there is no discussion of the coherence of the fibers. Court contains no disclosure of any measurement of the fiber coherence or any data which describes chitosan fibers having any of the characteristics of Applicant's invention. Furthermore, there is no teaching or suggestion in Court of the length to width proportion of the fibers (as in claim 3) or the different types of wound dressings (as in claim 7).

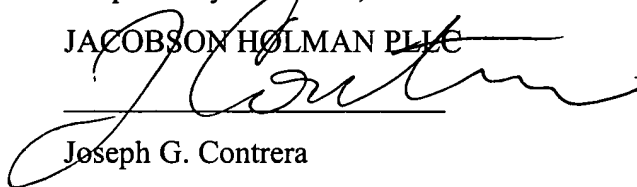
"To support the conclusion that the claimed invention is directed to obvious subject matter, either the references must expressly or impliedly suggest the claimed invention or the examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious in light of the teachings of the references." Ex parte Clapp, 227 USPQ 972, 973 (Bd. Pat. App. & Inter. 1985). Findings of fact must be supported by substantial evidence in the record. In re Gartside, 203 F.3d 1305, 1315, 53 USPQ2d 1769, 1775 (Fed. Cir. 2000).

With regard to claims 3 and 7, the Examiner has not provided any references containing a detailed enabling methodology, a suggestion to modify the prior art to produce the claimed invention, or any evidence suggesting the modification would be successful. The Applicant therefore requests the rejection be withdrawn.

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all currently outstanding rejections, and that they be withdrawn. As such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Respectfully submitted,

JACOBSON HOLMAN PLLC

A handwritten signature in black ink, appearing to read 'J. Contrera', is written over a horizontal line.

Joseph G. Contrera

Registration No. 44,628

400 Seventh Street, N.W.

Washington, D.C. 20004-2201

(202) 638-6666

Date: April 14, 2004

Atty. Docket: 11072/P67699US0

HBJ/JGC